DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFI-35 5/6/97

M869N

Food and Drug Administration
Seattle District
Pacific Region
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Bothell WA 98041-3012

Telephone: 206-486-8788
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April 29, 1997

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 97-18

WARNING LETTER

Ronald A. Andersen
Andersen Dairy
305 East Main Street
Battle Ground, Washington 98604

Dear Mr. Andersen:

An investigation at your dairy operation located at Vancouver, Washington, conducted on January 15 to February 13, 1997, confirmed that you offered an animal for sale for food in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On November 4, 1996, you sold a bull calf, identified with back tag number 920X7028, for slaughter as human food at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 15.0 ppm of streptomycin in the kidney. A tolerance of 2.00 ppm has been established for residues of streptomycin in edible tissues of calves.

[redacted] brand of [redacted] with spectinomycin as the active ingredient, is commonly reported by the USDA laboratory as streptomycin. Streptomycin and spectinomycin are in the same class of drugs and USDA commonly reports the most commonly used drug in a class of drugs.. Further analysis by FDA laboratory confirmed the presence of spectinomycin. There has been no tolerance established for residues of spectinomycin in edible tissues of calves. The presence of this drug in edible tissues from this calf causes the food to be adulterated within the meaning of Section 402(a)(2)(D) of the Act.

Our investigation also found that you hold animals under conditions which allow medicated animals bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system a) for assuring that animals have been treated only with drugs which have been approved for use in those species; b) for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; c) and for

assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the Act.

You are adulterating the drug [redacted] brand of spectinomycin that your farm uses on cows within the meaning of section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug in a species for which it is not approved causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step being taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Richard S. Andros, Compliance Officer, at the above address.

Sincerely yours,

Marlee M. Wekell Jr/

Roger L. Lowell
District Director